

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF NEW YORK**

JANE DOE, et al.

Plaintiffs,

vs.

HOWARD ZUCKER, et al.

Defendants.

Civil Action No.: 1:20 – CV – 0840  
(BKS/CFH)

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF  
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

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**TABLE OF CONTENTS**

TABLE OF CONTENTS.....	i
TABLE OF AUTHORITIES.....	iii
PRELIMINARY STATEMENT.....	2
STATEMENT OF FACTS.....	3
<b>ARGUMENT: THE COURT SHOULD STAY THE NEW REGULATIONS CONTAINED IN 10 NYCRR §66-1 AND PRELIMINARILY ENJOIN THE DEFENDANTS FROM EXCLUDING STUDENTS FROM SCHOOL IF THEY HAVE SUBMITTED A MEDICAL EXEMPTION FROM A PHYSICIAN LICENSED IN NEW YORK.....</b>	<b>9</b>
<b>I: PLAINTIFFS MEET AND EXCEED REQUIREMENTS FOR PRELIMINARY     INJUNCTION.....</b>	<b>9</b>
a. PLAINTIFFS HAVE A HIGH LIKELIHOOD OF SUCCESS ON THE MERITS.....	10
i. The challenged regulations and policies are unconstitutional under any standard of review.....	10
ii. The challenged policies violate fundamental human rights and are not narrowly tailored to serve a compelling government interest.....	13
iii. The challenged policies are unconstitutional under <i>Jacobson</i> and fail even a rational basis review.....	17
b. PLAINTIFFS WILL SUFFER IMMEDIATE IRREPARABLE HARM AND LEGAL REMEDIES WILL NOT SUFFICE.....	22
c. THE BALANCE OF HARDSHIPS DECISIVELY FAVORS PLAINTIFFS.....	22

d. THE PUBLIC INTEREST IS SERVED IN PROTECTING THE RIGHTS OF MEDICALLY FRAGILE CHILDREN TO ATTEND SCHOOL .....	23
----------------------------------------------------------------------------------------------------------------------	----

<b>II: PLAINTIFFS MEET AND EXCEED REQUIREMENTS FOR PRELIMINARY INJUNCTION.....</b>	<b>24</b>
----------------------------------------------------------------------------------------	-----------

<b>CONCLUSION.....</b>	<b>24</b>
------------------------	-----------

## TABLE OF AUTHORITIES

### Cases

<i>Bailey’s Campground Inc. v. Mills,</i> 2020 WL 2791797 (D.Me.) .....	13
<i>Brown v. Board of Education,</i> 347 U.S. 483 (1954).....	23
<i>Catanzano v. Dowling,</i> 847 F. Supp. 1070 (W.D.N.Y. 1994).....	22
<i>Cruzan v. Director, Missouri Department of Health,</i> 497 U.S. 261 (1990).....	14
<i>Dugan v. State,</i> 2019 WY 112 (Wyo. 2019) .....	12
<i>Dugan v. State,</i> 2020 WL 1124448 (U.S. 2020).....	12
<i>Heldman on Behalf of T.H. v. Sobol,</i> 962 F.2d 148 (2d Cir. 1992).....	22
<i>Jacobson v. Massachusetts,</i> 197 U.S. 11 (1905).....	11, 12, 17, 18, 19, 21
<i>Kenniston v. Department of Youth Services,</i> 453 Mass. 179 (2009) .....	12
<i>Meyer v. Nebraska,</i> 262 U.S. 390 (1923).....	14
<i>Parham v. J.R.,</i> 442 U.S. 584 (1979).....	14, 15
<i>Phillips v. City of New York,</i> 775 F.3d 538 (2d Cir. 2015).....	13
<i>Pierce v. Society of Sisters,</i> 268 U.S. 510 (1925).....	14

<i>Saget v. Trump</i> , 375 F. Supp. 3d 280 (E.D.N.Y. 2019) .....	9
<i>Steinberg v. Carhart</i> , 530 U.S. 914 (2000).....	16, 21
<i>Troxel v. Granville</i> , 530 U.S. 57 (2000).....	14, 15
<i>Union Pacific Railway Company v. Botsford</i> , 141 U.S. 250 (1891).....	14
<i>Washington v. Glucksberg</i> , 521 U.S. 702 (1997).....	11, 13
<i>Washington State Grange v. Washington State Republican Party</i> , 552 U.S. 442 (2008).....	12
<i>Winter v. N.R.D.C.</i> , 555 U.S. 7 (2008).....	9, 10
<i>Wisconsin v. Yoder</i> , 406 U.S. 205 (1972).....	14
<i>Zucht v. King</i> , 260 U.S. 174 (1922).....	11, 12
<b><u>Statutes</u></b>	
20 U.S.C. § 1400.....	13
N.Y. P.H.L. §2100 .....	9, 23
N.Y. P.H.L. §2164 .....	4
N.Y. P.H.L. §2164[8].....	9
<b><u>Federal Rules of Civil Procedure</u></b>	
Fed. R. Civ. P. 65 .....	1

**Regulations**

10 NYCRR §66-1 .....	1, 9, 25
10 NYCRR §66-1.1 .....	4
10 NYCRR §66-1.2(ii)(4) .....	6
10 NYCRR §66-1.3(c) .....	6, 7
10 NYCRR §66-1.10 .....	9, 23

**Other Authorities**

FADEN ET AL., <i>TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW</i> No. 10, at 181-82 (1997), A HISTORY AND THEORY OF INFORMED CONSENT 156-57 (1986) .....	10, 11
James G. Hodge & Lawrence O. Gostin, <i>School Vaccination Requirements: Historical, Social, and Legal Perspectives</i> , 90 Ky. L.J. 831, 844 (2001-2002) .....	3
Stephen A. Siegel, <i>The Origin of the Compelling State Interest Test and Strict Scrutiny</i> , 48 Am. J. Legal Hist. 355, 355-56 (2006) .....	12

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF**  
**TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

By and through their counsel and pursuant to F.R.Civ.P. 65, plaintiffs respectfully submit this Memorandum of Law in support of their Motion for a TRO and a Preliminary Injunction, enjoining Defendants, the New York State Department of Health, its agents and assigns, and the named and unnamed school principals, superintendents and New York State school districts, from implementing regulations, policies and practices that unconstitutionally burden families, place medically fragile children at risk of harm by requiring them to ignore the advice of their trusted licensed physicians or lose the right to attend school, and violate multiple federal laws, including the Individuals with Disabilities Education Act, 20 U.S.C. § 1400 *et seq.* ("IDEA") and the Rehabilitation Act of 1973.

By this motion and pending resolution of this matter or further interim order of this Court, plaintiffs respectfully request that this Court:

- 1) Stay the new regulations pertaining to the medical exemption from school immunization requirements codified in 10 NYCRR §66-1;
- 2) Enjoin defendants from excluding children from school due to lack of immunization if such child has presented a certification from a licensed physician advising against such immunization; and
- 3) Order the Defendants to provide notice to schools, districts, and families that Plaintiffs and similarly situated children may attend school and access federally protected programs; and
- 4) Issue a temporary restraining order granting the same relief for fourteen days from the start of school pending hearing on the motion; and

1  
2 5) For such other and further relief as the Court deems just and appropriate.  
3

4 **PRELIMINARY STATEMENT**

5 Last year, the New York State Department of Health adopted unconstitutional regulations,  
6 resulting in the expulsion of hundreds of medically fragile children from New York schools and  
7 daycare centers.

8 The new regulations empower and encourage school principals to overrule licensed treating  
9 physicians, disallow school attendance, and remove children from school unless their parents  
10 agree to contravene the advice of their trusted licensed physicians and subject their children to  
11 risk of serious harm. They further violate the fundamental rights of hundreds more by imposing  
12 unconstitutional conditions on their ability to obtain a medical exemption and attend school.  
13

14 This motion seeks to allow these medically fragile children to remain in school pending  
15 resolution of this matter as long as they present a certificate from a physician licensed to practice  
16 medicine in New York as to the significant risk posed by immunizations to their health and to  
17 stay the implementation of the regulations that place additional unconstitutional burdens on the  
18 exemption process as detailed below.  
19

20 Particularly now, when schools across New York have adopted rigorous social distancing,  
21 mask wearing, sanitation and have implemented online education capabilities to quell the spread  
22 of Covid-19, there is no basis for the claim that these children, who make up less than half of  
23 one percent of all school children in New York, pose a threat to other children sufficient to  
24 justify denying them an education as this litigation progresses. To the contrary, plaintiffs'  
25 children are seriously harmed if Defendants are permitted to deny them the right to participate  
26  
27

1  
2 in school and receive needed educational services. As detailed below, Plaintiffs meet the  
3 requirements for preliminary injunctive relief and respectfully ask this Court to issue the  
4 temporary relief requested.  
5

6 **STATEMENT OF FACTS**

7 New York State justifies mandatory school vaccination by asserting that it protects those  
8 children who cannot safely or effectively benefit from vaccines through “herd immunity.” The  
9 theory of herd immunity is that if enough healthy children are vaccinated, then these medically  
10 fragile children will have a buffer from contracting the disease.  
11

12 New York, along with every state in the country as required by law, provides a medical  
13 exemption to the mandatory vaccine requirements for school admission. James G. Hodge &  
14 Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal*  
15 *Perspectives*, 90 Ky. L.J. 831, 844 (2001-2002).  
16

17 New York codifies the medical exemption in New York Public Health Law §2164[8], stating:  
18 “If any physician licensed to practice medicine in this state certifies that such immunization may  
19 be detrimental to a child’s health, the requirements of this section shall be inapplicable until  
20 such immunization is found no longer to be detrimental to the child’s health.” (*emphasis added*).  
21

22 Before August 2019, pursuant to this public health statute, students who sought the medical  
23 exemption submitted a simple letter from a physician licensed in New York, certifying that one  
24 or more of the mandatory vaccines might cause the child harm and specifying for how long the  
25 student should be exempt from that requirement. This process was consistent with the types of  
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1  
2 forms and certifications that students are asked to submit for other medical documentation in  
3 school, such as a doctor's note for absence, fitness for sports, or accommodation.  
4

5 On August 16, 2019, the New York State Department of Health ("NYSDOH") promulgated  
6 new regulations that unconstitutionally burden the availability of the medical exemption for  
7 eligible medically fragile children, effectively making it unavailable for all but an arbitrarily  
8 narrow subset of children. New York Codes, Rules and Regulations (10 NYCRR §66-1). See  
9 Gibson Dec. at ¶¶10-12.  
10

11 First, a newly created subdivision (l) of section 66-1.1 limits what "may be detrimental to  
12 the child's health" for purposes of PHL §2164, now requiring a physician to certify that a child  
13 has a medical contraindication or precaution that fits within the narrow confines of the Centers  
14 for Disease Control and Prevention ("CDC") Advisory Committee on Immunization Practices  
15 guidelines ("ACIP guidelines")<sup>1</sup>. This removes discretion from treating physicians and excludes  
16 hundreds of recognized potential harms that vaccinations can cause and that have led physicians  
17 to contraindicate them.  
18

19 Specifically, as applied, the new regulations recognize only the three reasons ACIP expressly  
20 articulates as "contraindications" as valid medical exemptions in New York. This is arbitrary  
21 because there are hundreds of well-established, known adverse reactions listed in manufacturers'  
22 vaccine package inserts; injuries and conditions compensated by the United States National  
23  
24

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25  
26 <sup>1</sup> Technically, the new subdivision provides that the definition could include "a medical contraindication or  
27 precaution to a specific immunization consistent with ACIP guidance or other nationally recognized evidence-  
28 based standard of care." In practice, only ACIP contraindications are considered by school districts.

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2  
3 Vaccine Injury Compensation Program; and reasons addressed in Institute of Medicine reports  
4 that expressly acknowledge subpopulations that have pre-existing susceptibilities to serious  
5 adverse reactions. Gibson Dec. at ¶¶ 12.

6 The CDC itself has repeatedly affirmed that the ACIP guidelines are not intended to serve as  
7 the basis for medical exemptions or supplant the clinical judgment of treating physicians. See,  
8 e.g., Doe Dec. at ¶27. Nonetheless, Defendants continue to overrule treating physicians on the  
9 grounds that the physicians' medical guidance does not fit within narrow contraindications in  
10 the ACIP guidelines.  
11

12 Second, the new regulations give school principals, who generally lack any medical training,  
13 authority to overrule the judgment expressed by these medically fragile children's licensed  
14 treating physicians. If the principals do not agree or understand how the exemption written by  
15 the child's physician fits into the complicated recommendations set forth by ACIP, the  
16 regulations authorize them to overrule doctors and exclude children from school.  
17

18 The regulations do not require school principals to consult with medical professionals before  
19 making these determinations. When they do so, the consulting physicians typically have never  
20 met the child in question or have never conducted a medical examination and, often, have not  
21 even spoken to the family, gathered the child's or the family's medical history or consulted with  
22 the treating physicians. Conversations that do take place between treating physicians and the  
23 school district consultants or reviewing entity tend to be intimidating and lead physicians to  
24 express hesitancy for fear of retaliation. See, e.g., Loe Dec. at ¶¶9-12 and ¶¶18-21. The  
25 consultants have conflicts of interest, since typically they have financial or professional  
26  
27

1  
2 incentives to deny as many applications as possible. They do not have any duty of care to  
3 individual children. Faced with differences of opinion between treating physicians and  
4 consultants, school principals cannot prudently weight the strength or sufficiency of the various  
5 positions.  
6

7 Third, the new regulations contain overburdensome requirements for doctors that deter  
8 physicians from writing medical exemptions, even when doctors have concluded that  
9 immunizations are unsafe for specific children. Doctors are no longer allowed to write their  
10 traditional doctor's "notes" but must submit specific forms "containing sufficient information to  
11 identify medical contraindication." NYCRR 66-1.3(c).  
12

13 Doctors provide this information to principals, who in turn share it with staff and consultants.  
14 Physicians must then upload the detailed personal and family health information to a statewide  
15 database, whether the family consents to sharing this sensitive health information or not.  
16 NYCRR 66-1.2(ii)(4). The NYSDOH has followed up by contacting many physicians, often  
17 intimidating them. Gibson Dec. at ¶¶12; Coe Dec. at ¶19.  
18

19 Due to these strictures, children who received medical exemptions to immunization for years  
20 suddenly find their physicians are no longer willing to submit to the burdens and intimidation  
21 associated with exemption letters. See, e.g., N.C. Dec. and Loe Dec.  
22

23 Families are being asked to put together voluminous and invasive medical records, some  
24 even having to retain counsel to help draft long and detailed medical exemption letters in  
25 coordination with treating physicians. Some families are told that certifications from licensed  
26 physicians are not enough –they need to secure corroborating exemptions from additional  
27

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3 medical specialists. This makes exemptions impossible for many families. Such specialists often  
4 have waiting lists of over a year. Families are typically given a few days to obtain additional  
5 specialists' exemptions. Worse, even for conditions that are permanent, the new regulations  
6 compel families to submit to this process annually, creating expense and uncertainty. See  
7 NYCRR 66-1.3(c) Families are put in a state of constant anxiety and limbo about whether their  
8 medically fragile children will suddenly be expelled from school, as so many others have been.  
9

10 Schools have to hire consulting doctors and attorneys and take up valuable time of school  
11 administrators and professionals to deal with medical exemptions that could be better spent on  
12 education.

13 Several lawsuits for individual plaintiffs have successfully challenged the arbitrary denial of  
14 medical exemptions. Hundreds of equally deserving children, however, lack the resources to  
15 bring individual legal challenges.  
16

17 If interim relief is not granted, plaintiff families and children will continue to sustain  
18 irreparable harm. We respectfully refer the Court to declarations of the named plaintiffs,  
19 additional class members and medical and educational providers. *See* August 2020 Declarations  
20 of Named Plaintiffs Jane Doe, Jane Boe, John Coe, John Foe, Jane Joe, and Jane Loe; Class  
21 Members A.M. 2, E.C., J.S., N.C., B.B., A.M.3, K.W., C.M., N.F., C.B., A.M., R.B., M.D., B.P.,  
22 R.F., M.N, S.P., J.H., and H.D.; and Lawrence Palevsky, M.D., and Jeanette Rodriguez. As the  
23 declarations detail, in addition to the harms from violation of fundamental constitutional rights  
24 and deprivation of educational opportunities and much-needed special education and therapeutic  
25 services, many children face deep psychological trauma as a result of the new regulations.  
26  
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2 Families have suffered financially; the stress has led to divorce in some families; and many  
3 parents and children have become clinically depressed. Some children have suffered physical  
4 harm as well.  
5

6 Plaintiffs pose no cognizable threat to other students. Many of the immunizations on the  
7 mandatory schedule from which these children seek exemption do not provide any “herd  
8 immunity” benefit. For example, tetanus is not a contagious disease, meaning that vaccines offer  
9 only personal protection. <https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html> (“Tetanus  
10 is not contagious from person to person.”) Similarly, other mandatory vaccines, including the  
11 vaccines mandated for Diphtheria, Pertussis, Polio, and Meningococcal disease, do not provide  
12 protection for anyone but the recipient. See Gibson Dec. at ¶¶ 14-15. For the mandatory vaccines  
13 that can provide protection from transmission, the risk posed by the tiny percentage of children  
14 who have submitted medical exemptions in New York is insignificant. Gibson Dec. at ¶¶ 16-18.  
15 Less than half of one percent of children in New York present a medical exemption to  
16 immunization, far below the herd immunity thresholds cited by even the most conservative  
17 estimates for public health protection.  
18  
19

20 This year, the risk is even less. The Covid-19 pandemic has forced New York Schools to  
21 adopt rigorous protective measures that will further vitiate any possible threat from these  
22 medically fragile children.  
23

24 Furthermore, it is unlikely that a medically fragile child could catch one of the vaccine  
25 preventable diseases for which vaccination can halt transmission. In the event that there was an  
26 outbreak of a vaccine preventable disease, New York Public Health Law contains narrowly  
27

tailored measures, such as quarantine of infected individuals (N.Y. PHL §2100) and temporary exclusion of unimmunized students (10 NYCRR § 66-1.10), to ensure public safety.

### **ARGUMENT**

#### **THE COURT SHOULD STAY THE NEW REGULATIONS CONTAINED IN 10 NYCRR §66-1 AND PRELIMINARILY ENJOIN THE DEFENDANTS FROM EXCLUDING STUDENTS FROM SCHOOL IF THEY HAVE SUBMITTED A MEDICAL EXEMPTION FROM A PHYSICIAN LICENSED IN NEW YORK**

Plaintiffs meet the requirements for preliminary injunctive relief and respectfully ask this Court to allow their children to return to school pending the resolution of this litigation.

#### **I. PLAINTIFFS MEET AND EXCEED PRELIMINARY INJUNCTION REQUIREMENTS**

Plaintiffs meet and exceed the criteria to support a TRO and preliminary injunction. Equitable injunctive relief is intended to preserve the *status quo*, i.e., the last point at which the parties' relationship to the issue was uncontested. *Saget v. Trump*, 375 F. Supp. 3d 280, 339 (E.D.N.Y. 2019) (citations omitted). A Court may issue a preliminary injunction at its discretion. *Id.*

Here, the *status quo* Plaintiffs seek to preserve is adherence to the plain language of N.Y. Public Health Law § 2164 [8], without the additional burdens the state defendants' new regulations [contained in NYCRR §66-1] imposed, which create impermissible and unconstitutional roadblocks to the Plaintiffs' safety and constitutional rights.

In the Second Circuit, "a party seeking a preliminary injunction must demonstrate: (1) irreparable harm to the party; (2) either (a) a likelihood of success on the merits or (b) both serious questions on the merits and a balance of hardships decidedly favoring the moving party; and (3) that the public interest favors issuing the preliminary injunction." *Id.*; see also *Winter*

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3 v. *N.R.D.C.*, 555 U.S. 7, 20 (2008). As shown below, Plaintiffs meet and exceed each  
4 requirement for injunctive relief and, therefore, respectfully request that the Court issue a TRO  
5 and then a preliminary injunction to avoid irreparable harm pending resolution of the litigation.

6 **a. PLAINTIFFS HAVE A LIKELIHOOD OF SUCCESS ON THE MERITS**  
7 **i. The challenged regulations and policies are unconstitutional under**  
8 **any standard of review**

9 In arbitrarily narrowing the definition of what “may cause harm” to a child and  
10 encouraging schools to overrule licensed physicians chosen by the parents of medically fragile  
11 children about what is safe, the state defendants have violated well-established fundamental  
12 constitutional rights of the plaintiffs, including the right to refuse medical treatment, the right  
13 of informed consent, fundamental privacy rights, the right of parents to direct the care and  
14 upbringing of their children, the right of students to receive an education, and the right to be  
15 free of unconstitutional conditions, which require the surrender of a constitutionally protected  
16 right in order to receive public benefits.  
17

18 Some of these rights are rooted not only in the legal and ethical traditions of this country  
19 but are also internationally recognized as fundamental human rights. The rights of informed  
20 consent and the related right to refuse unwanted medical interventions, for example, are not  
21 only deeply rooted in myriad ethical, philosophical and legal foundations of this nation, but  
22 are the pivotal principles articulated by the Nuremberg Declaration and form the basis for  
23 internationally recognized fundamental human rights protections. *See, e.g.*, TRIALS OF WAR  
24 CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL  
25 COUNCIL LAW No. 10, at 181-82 (1997) [hereinafter TRIALS OF WAR CRIMINALS  
26  
27  
28

1  
2 BEFORE THE NUERNBERG MILITARY TRIBUNALS]; FADEN ET AL., A HISTORY  
3 AND THEORY OF INFORMED CONSENT 156-57 (1986); see also *Washington v.*  
4 *Glucksberg*, 521 U.S. 702, 703 (1997)(“The constitutionally protected right to refuse lifesaving  
5 hydration and nutrition that was discussed in *Cruzan*...was not simply deduced from abstract  
6 concepts of personal autonomy, but was instead grounded in the Nation's history and traditions,  
7 given the common-law rule that forced medication was a battery, and the long legal tradition  
8 protecting the decision to refuse unwanted medical treatment.”)  
9  
10

11       Mandatory school vaccination has had a controversial history in the United States and  
12 abroad. At the crux of public debate are core concerns about the tradeoffs between the state’s  
13 use of its police powers to protect the public from communicable disease versus the  
14 infringements on fundamental individual and parental rights. In recognition of these human  
15 rights issues, many countries, including Sweden, Spain, the United Kingdom and Japan, do not  
16 legally mandate school vaccines.  
17

18       The legal justification for vaccine mandates in the United States is based on the 1905  
19 Supreme Court decision *Jacobson v. Massachusetts*, which held that the state’s police powers  
20 give the state “the right to protect itself against an epidemic of disease which threatens the  
21 safety of its members.” *Jacobson v. Massachusetts*, 197 U.S. 11 (1905); affirmed by *Zucht v.*  
22 *King*, decided in 1922, citing *Jacobson* to deny jurisdiction over the plaintiffs’ equal protection  
23 argument regarding a preemptive school vaccine mandate as beyond the power of the Court to  
24 review by writ. *Zucht v. King*, 260 U.S. 174 (1922). These are the only two Supreme Court  
25 cases addressing the constitutionality of mandatory vaccination, and they both substantially  
26  
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1  
2 predate Nuremburg and the strict scrutiny frameworks that now define and protect fundamental  
3 constitutional rights.  
4

5 While *Jacobson* remains precedent that mandatory vaccination is within the state's  
6 police powers as a compelling state interest, the Supreme Court's lax approach to other liberty  
7 infringements (except economic ones) during the *Lochner* era (during which *Jacobson* and  
8 *Zucht* were decided) has long since been replaced by a strict scrutiny analysis for fundamental  
9 constitutional rights. See generally Stephen A. Siegel, *The Origin of the Compelling State*  
10 *Interest Test and Strict Scrutiny*, 48 Am. J. Legal Hist. 355, 355-56 (2006) (providing a  
11 comprehensive history of strict scrutiny review and tracing its development in the Warren  
12 Court).  
13

14 In modern jurisprudence, laws that severely or substantially burden, infringe on, or  
15 significantly interfere with the exercise of a fundamental constitutional right are subject to  
16 review under a standard of strict judicial scrutiny, requiring a compelling state interest and  
17 objectives that could not be achieved by less restrictive measures. *Washington State Grange v.*  
18 *Washington State Republican Party*, 552 U.S. 442 (2008); *Kenniston v. Department of Youth*  
19 *Services*, 453 Mass. 179 (2009); *Dugan v. State*, 2019 WY 112, 451 P.3d 731 (Wyo. 2019),  
20 cert. denied, 2020 WL 1124448 (U.S. 2020).  
21  
22

23 The issue before the Court is not whether the state is able to mandate vaccines for  
24 school children. Rather, it is whether the state and the defendant actors have adopted overbroad  
25 policies and procedures that unduly burden fundamental rights and the ability of medically  
26 fragile children to obtain a medical exemption from school vaccines in cases where licensed  
27

1  
2 physicians have determined that the vaccines may put them at risk of serious or even fatal harm.  
3  
4 Whether analyzed under the older *Jacobson* standard or under a modern strict scrutiny  
5 approach, the challenged policies are unlikely to survive scrutiny.

6 **ii. The challenged policies violate fundamental constitutional rights**  
7 **and are not narrowly tailored to serve a compelling government**  
8 **interest**

9 The state has a compelling interest in protecting public health from urgent outbreaks of  
10 vaccine-preventable disease, including through the imposition of school vaccine requirements  
11 with appropriately tailored exemptions. *Phillips v. City of New York*, 775 F.3d 538, 540 (2d  
12 Cir. 2015)(upholding dismissal of plaintiffs substantive due process claim against school  
13 vaccine mandates and noting that New York law provided robust religious and medical  
14 exemptions).

15  
16 To assess whether the infringements on fundamental rights are appropriately tailored, a  
17 recent Federal Court decision clarified that a court must look beyond *Jacobson* and examine the  
18 modern jurisprudence regarding the rights at stake. *Bailey's Campground Inc. v. Mills*, 2020  
19 WL 2791797 (D.Me.)(holding that *Jacobson*, decided over 100 years ago, does not define the  
20 standard of review for infringement of a fundamental constitutional right and that Courts must  
21 review the modern jurisprudence analyzing infringement upon fundamental rights through tiers  
22 of scrutiny according to subsequent case law regarding the fundamental right at issue).

23  
24 Since the *Lochner* era, Courts have determined that the Fourteenth Amendment Due  
25 Process Clause contains heightened protections against government interference with certain  
26 fundamental rights and liberty interests. *Washington v. Glucksberg*, 521 U.S. 702 (1997).

1  
2 Multiple fundamental rights are at stake in this case.

3  
4 It is well established that a patient must give informed consent before a physician may  
5 administer treatment. The U.S. Supreme Court recognized the right to refuse unwanted medical  
6 treatment as early as 1891 in *Union Pacific Railway Company v. Botsford*: “no right is held  
7 more sacred, or is more carefully guarded, by the common law, than the right of every  
8 individual to the possession and control of his own person, free from all restraint or interference  
9 of others.” *Union Pacific Railway Company v. Botsford*, 141 U.S. 250 (1891). The Supreme  
10 Court has reaffirmed this principle on several occasions, most recently in *Cruzan v. Director,*  
11 *Missouri Department of Health*: “a competent person has a constitutionally protected liberty  
12 interest in refusing unwanted medical treatment.” *Cruzan v. Director, Missouri Department of*  
13 *Health*, 497 U.S. 261 (1990).

14  
15 Our constitution also empowers parents and guardians to exercise the right of informed  
16 consent on behalf of their minor children. *See, e.g. Meyer v. Nebraska*, 262 U.S. 390 (1923),  
17 *Pierce v. Society of Sisters*, 268 U.S. 510 (1925), *Wisconsin v. Yoder*, 406 U.S. 205 (1972),  
18 *Parham v. J.R.*, 442 U.S. 584 (1979). Parents hold rights to direct the care and upbringing of  
19 their children. According to the Supreme Court, “the interest of parents in the care, custody, and  
20 control of their children—is perhaps the oldest of the fundamental liberty interests recognized  
21 by this Court.” *Troxel v. Granville*, 530 U.S. 57, 65 (2000).

22  
23 While such a right is not unlimited, “[t]here is a presumption that fit parents act in their  
24 children’s best interests” and thus “there is normally no reason for the State to inject itself into  
25 the private realm of the family to further question fit parents’ ability to make the best decisions  
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2 regarding their children.” *Id.* at 58. Here, where the parent plaintiffs have not been found unfit,  
3 and they logically wish to follow the medical advice of their licensed physician, the state has no  
4 valid reason to intervene.  
5

6 In cases where the school district consultant has a difference of opinion about what  
7 might harm a child, deference should go to the parents, who have the ultimate right and  
8 responsibility to decide, within reason, which medical advice to follow. In *Parham v. J.R.*, the  
9 Supreme Court held that parents have a “‘high duty’ to recognize symptoms of illness and seek  
10 and follow medical advice” for their children. Further, the Court held that the state does not  
11 have the authority to take these decisions away from the parents. “Simply because the decision  
12 of the parent...involves risks does not automatically transfer the power to make that decision  
13 from the parents to some agency or officer of the state. The same characterizations can be made  
14 for a tonsillectomy, appendectomy, or other medical procedure...Parents can and must make  
15 those judgments.” *Id.* at 604. The Court went on to stress that: “Neither state officials nor  
16 federal courts are equipped to review such decisions.” *Id.* Certainly, under this standard, school  
17 principals are not equipped to review these decisions or weigh conflicting medical advice, and  
18 they should not wield this authority.  
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22 The fact that there exist differences of medical opinion about the risk of immunization to  
23 a particular child does not give the state the right to preclude the parents from following the  
24 advice of their trusted physicians in such decisions. Evaluations of what may cause harm cannot  
25 require absolute certainty or unanimity of medical opinion. “Doctors often differ in their  
26 estimation of comparative health risks and appropriate treatment. And *Casey’s* words  
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2 “appropriate medical judgment” must embody the judicial need to tolerate  
3 responsible differences of medical opinion.” *Steinberg v. Carhart*, 530 U.S. 914, 937 (2000)  
4 (finding that a state statute banning partial birth abortion did not contain a sufficiently robust  
5 health exemption to allow for differences of medical opinion about the necessity of using the  
6 banned procedure to protect a woman’s health). As the Supreme Court recognized in *Steinberg*,  
7 a difference of medical opinion tends to signify the presence of risk, not its absence, counseling  
8 against inflexible state-imposed risk assessments. *Id.*  
9  
10

11 Here, the state should afford the same deference to parents and providers to ensure  
12 children’ safety. Some of the plaintiffs have lost family members to proven adverse vaccine  
13 reactions. Some of them have experienced severe injuries. Most of them are immune-  
14 compromised, and all of them risk severe injury or even death from vaccines due to their  
15 medical conditions per their licensed physicians. While there may not be unanimity of risk  
16 assessment, the fact that parents need to obtain the certification of a licensed medical  
17 provider should be sufficient. This is consistent with the New York State legislature’s  
18 language, which provides that if *any* licensed physician determines that the vaccine may be  
19 harmful, that child should be medically exempt.  
20  
21

22 Requiring unanimity of opinion, arbitrarily narrowing health exemption criteria and  
23 overruling parents who have corroborating certifications from licensed treating doctors is  
24 subjecting medically fragile children to serious risk. The new regulations also burden  
25 medical privacy and create such onerous documentation burdens that physicians are  
26 unwilling to sign medical exemptions even in cases where they assert that the exemption is  
27

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2 necessary to protect the child. These regulations are not rationally related to the state's  
3 interest in keeping the community safe from communicable disease, leave aside narrowly  
4 tailored enough to survive strict scrutiny considering the liberty interests at stake.  
5

6 **iii. The challenged policies are unconstitutional under *Jacobson* and fail**  
7 **even a rational basis review**

8 Lower tiers of scrutiny exist for rights that are not considered fundamental, ranging from  
9 intermediate scrutiny to the “rational basis” test, which would require a court to strike down an  
10 infringing regulation if it is arbitrary and capricious.

11 *Jacobson* essentially applied a rational basis test, as heightened scrutiny for the liberty  
12 interests at stake had not yet been developed. Even under this older and more deferential  
13 standard, the Court stressed that if the mandate posed a threat to the health of an individual, it  
14 would be unconstitutional. *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 38–39  
15 (1905).  
16

17 The case before the Court involved a statute that imposed a \$5 fine on the plaintiff for  
18 refusing to comply with a compulsory smallpox vaccination mandate during a deadly smallpox  
19 pandemic. No other penalty was at issue, and the plaintiff was never at risk of being force  
20 vaccinated.  
21

22 The *Jacobson* Court did not recognize unlimited authority for the constitutionality of  
23 all vaccine mandates. According to the Court, utilization of state police powers in support of  
24 vaccination requirements or other public health initiatives is constitutionally permissible only  
25 if the powers exercised conform with these five principles:  
26

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2  
3 (1) *public health necessity*—Police powers must be based on the “necessity of the  
4 case” and may not be justified “under the pressure of great dangers” to the safety  
5 of the “general public” and may not go “beyond what was reasonably required for  
6 the safety of the public;” *Jacobson*, 197 U.S. at 28;

7 (2) *reasonable means*—The *Jacobson* Court introduced a means/ends test that  
8 requires a reasonable relationship between the public health intervention and the  
9 achievement of a legitimate public health objective. *Id.* at 26. Even though the  
10 objective of the legislature may be valid and beneficent, the state’s methods must  
11 have a “real or substantial relation” to protect the public health and cannot be “a  
12 plain, palpable invasion of rights”; *Id.* at 31;

13 (3) *proportionality*—“[T]he police power of a State,” said Justice Harlan, “may be  
14 exerted in such circumstances or by regulations so arbitrary and oppressive in  
15 particular cases as to justify the interference of the courts to prevent wrong and  
16 oppression.” *Jacobson*, 197 U.S. at 38-39. Thus, a public health regulation may be  
17 unconstitutional if the intervention is gratuitously onerous or unfair; and

18 (4) *harm avoidance*—While those who pose a risk to the community can be required  
19 to submit to compulsory measures, including vaccination, for the common good,  
20 the measure itself should not pose a health risk to its subject.  
21

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23  
24 This last point was so important that the Court closed the decision by repeating and  
25 emphasizing that its holding could not extend in cases where the subject may be at risk of  
26 harm. Where it was reasonably likely that a person was “not a fit subject of vaccination or  
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2 that vaccination, by reason of his then condition, would seriously impair his health”,  
3  
4 mandating vaccines for this individual would be “cruel and inhuman in the last degree” and  
5 would not be upheld. *Id.* 38-39.

6 The case before us squarely addresses the type of overreach against which the *Jacobson*  
7 Court expressly warned. Here, plaintiffs are children whose licensed medical professionals have  
8 determined that they are at risk of serious harm from one or more mandatory vaccines. To force  
9 these families, who have all suffered so much already, to play Russian roulette and vaccinate  
10 vulnerable children despite the acknowledged risk is “cruel and inhuman to the last degree.”  
11 The challenged regulation fails every aspect of the *Jacobson* test.  
12

13 First, defendants’ policies, procedures and practices are not grounded in necessity. New  
14 York requires students to receive dozens of vaccines doses, whether any outbreak of disease is  
15 present or even reasonably likely. Moreover, advances in science have established that many  
16 mandatory vaccines, including required vaccines for tetanus, pertussis, diphtheria, meningitis,  
17 and polio, are unable to provide protection to the community. For these vaccines, which are the  
18 only ones many children are missing, there is no argument for necessity, particularly when the  
19 vaccine in question has been certified by the child’s licensed physician as carrying more risk  
20 than benefit for that child.  
21

22  
23 There is little evidence for those vaccines that can stop transmission, such as the live  
24 vaccines for measles, mumps, rubella and chickenpox, that the small percentage of children who  
25 seek a medical exemption, less than one half of one percent in New York, would pose any  
26 cognizable threat. Though there are occasional outbreaks, even in fully vaccinated populations,  
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1  
2 there are no current outbreaks, and there are less restrictive means for mitigation that exist –  
3 such as provisions to keep unvaccinated students at home during a school outbreak.  
4

5 Particularly now, when the Covid-19 pandemic requires all schools to exercise extensive  
6 protections – such as social distancing measures, mask wearing, increased sanitation of all  
7 surfaces, daily temperature checks, and provisions for home instruction in case of any outbreak  
8 of disease or suspected disease in an individual or in the community – the risk of this small  
9 percentage of children with medical exemptions catching and passing on a vaccine preventable  
10 disease is so low as to be virtually non-existent.  
11

12 Second, defendants have not adopted reasonable means. Redefining what “may  
13 constitute harm” on narrow and arbitrary standards that do not recognize even a fraction of the  
14 potential harms acknowledged by the vaccine manufacturers themselves, leave aside the  
15 extensive list of potential harms acknowledged by the federal government, the Institutes of  
16 Medicine, and the scientific literature, is unreasonable. Even the CDC acknowledges that the  
17 ACIP guidelines are no substitute for the clinical judgment of a provider who is familiar with  
18 the child’s individual and family medical history.  
19

20 Allowing school principals, with no medical training or expertise, to overrule the  
21 opinion of licensed physicians and medical providers is irrational. Even if the principal consults  
22 with a medical professional, the judgment of such a consultant, who has no duty of care to the  
23 particular child or family, and who is not in the position to have impartially assessed the child’s  
24 individual and family medical factors fully, is in no way superior to the judgment of the treating  
25 physician.  
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3 Third, the harms that the challenged practices inflict against medically fragile children  
4 and their families are disproportionate to the potential benefits and so arbitrary and oppressive  
5 as to justify the interference of this Court. School principals simply are not equipped to overrule  
6 medical decisions. To the extent that the state is attempting to further a legitimate interest of  
7 protecting the “herd” from communicable disease, this goal is not reasonably tailored to prevent  
8 disproportionate harm to these families. The state policies -- to require multiple corroborating  
9 opinions from specialists; to find doctors willing to write thirty-page medical opinions; to  
10 preference the opinions of non-treating consultants over treating physicians; to narrow the  
11 available reasons to exclude serious acknowledged risks; to violate the privacy of these  
12 families; and to deprive hundreds of children from pursuing an education in any private or  
13 public school -- are unnecessary, unreasonable, harmful, discriminatory, disproportionate, and  
14 arbitrary.  
15  
16

17 Fourth, *Jacobson* expressly states that where the plaintiff is not a fit subject for  
18 vaccination, it is unconstitutional to require it. The state cannot artificially narrow which  
19 children may be at risk to cases of unanimous opinion. The word of a licensed physician should  
20 be enough to support a family’s exemption determination. *Steinberg v. Carhart*, 530 U.S. 914,  
21 937 (2000). Moreover, doctors need to be able to make clinical determinations and take into  
22 account the hundreds of well-documented and recognized potential harms from vaccines instead  
23 of adopting the inflexible and narrow set of ACIP contraindications as the only measure.  
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2 Since the regulation and practices do not meet either the *Jacobson* test leave aside the  
3 more stringent strict scrutiny evaluation that must apply to each fundamental right at issue,  
4 Plaintiffs are unlikely to succeed on the merits.  
5

6 **b. PLAINTIFFS WILL SUFFER IMMEDIATE, IRREPARABLE HARM**  
7 **AND SUBSEQUENT LEGAL REMEDIES WILL NOT SUFFICE**

8 The violation of fundamental rights constitutes irreparable harm. *See Heldman on Behalf*  
9 *of T.H. v. Sobol*, 962 F.2d 148, 155-56 (2d Cir. 1992); *cf. Catanzano v. Dowling*, 847 F. Supp.  
10 1070, 1080 (W.D.N.Y. 1994)(“Generally, ‘for preliminary injunction purposes ... harm arising  
11 from a possible deprivation of ...constitutional rights’ that cannot be rectified by an award of  
12 damages is sufficient to demonstrate irreparable harm.”). Further, irreparable harm signifies an  
13 “injury which is actual and imminent, and which cannot be adequately compensated by a  
14 monetary award.” *Catanzano*, 847 F. Supp. at 1080. The new NYSDOH regulations are  
15 unconstitutional on their face and deprive parents and children of multiple fundamental  
16 constitutional rights.  
17

18  
19 Moreover, each day that these children’s exclusion from school and services continues,  
20 the inherent irreparable harm to them grows. As the attached declarations show, students are  
21 suffering academically, psychologically, physically, and emotionally from the denial, or threat  
22 of denial, of an education. Students who succumb to the state’s unconstitutional conditions and  
23 vaccinate against medical advice may also suffer permanent physical injury or death.  
24

25 **c. THE BALANCE OF HARDSHIPS DECISIVELY FAVORS PLAINTIFFS**

26 Plaintiffs seek to preserve the *status quo* that existed for over fifty years pending this  
27 litigation’s outcome. Without an injunction, hundreds of medically fragile children and their  
28 PAGE | 22

1  
2 families will continue to be harmed. The defendants face no similar hardship if the injunction is  
3 granted. In fact, Defendants will free up resources for education that they are now spending to  
4 scrutinize and defeat medical exemptions.  
5

6 Allowing these children to receive the same education as their peers pending resolution poses  
7 no cognizable threat. Outbreaks of vaccine-preventable disease are rare. Current measures to  
8 protect against Covid-19 make it all but impossible that these children could pose a threat.  
9

10 In the event that there was an outbreak of a vaccine preventable disease, New York Public  
11 Health Law contains less onerous, narrowly tailored measures to protect students. (N.Y. PHL  
12 §2100) and (10 NYCRR § 66-1.10).

13 **d. THE PUBLIC INTEREST IS SERVED IN PROTECTING THE RIGHTS**  
14 **OF MEDICALLY FRAGILE CHILDREN TO ATTEND SCHOOL**

15 In *Brown v. Board of Education*, the Supreme Court acknowledged that education is the  
16 most important function of state and local governments and that education and that education is  
17 a right of every child:  
18

19 Today, education is perhaps the most important function of state and local  
20 governments. In these days, it is doubtful that any child may reasonably be  
21 expected to succeed in life if he is denied the opportunity of an education. Such  
22 an opportunity, where the state has undertaken to provide it, is a right which  
23 must be made available to all on equal terms. 347 U.S. 483, 493 (1954).

24 Denying medically fragile children the right to attend school and placing undue burden  
25 on their ability to receive a medical exemption does not protect the community. The public is  
26 not served by having school principals, uneducated in healthcare, decide whether to honor a  
27 treating physician's recommendation. The public is not served by paying hundreds of  
28 thousands of dollars on high-priced consultants and attorneys to assist school principals make

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2 medical decisions. The public is not served by requiring vulnerable and overstressed families  
3 to gather multiple recommendations from specialists, leave their jobs, and spend thousands of  
4 dollars enforcing their medical exemption rights. While there might be the occasional  
5 physician who gets it wrong, the risk that unqualified school principals will put children in  
6 harm's way is far greater.  
7

8 Parents are in the best position to evaluate the medical advice of their providers and  
9 decide what is best for their child, within reasonable parameters. They love their child and best  
10 know the child's medical history, family history and unique health challenges. The law  
11 presumes and requires parents to act in the child's best interests. Public policies favor strong  
12 constitutional protections for parental decision-making, absent findings of neglect or abuse.  
13

14 Particularly now in the era of Covid-19, the public is best served by allowing these  
15 children to attend school and receive needed services.  
16

17 **II. PLAINTIFFS RESPECTFULLY REQUEST A TEMPORARY**  
18 **RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

19 Plaintiffs respectfully ask this Court to issue a temporary restraining order which stays  
20 the new regulations and prevents schools from overruling a certification from any physician that  
21 one or more vaccine may cause a child harm to provide time for the Court to hear this motion  
22 for a preliminary injunction granting the relief requested until the conclusion of this litigation.  
23

24 **CONCLUSION**

25 For the aforementioned reasons, while this litigation is pending, Plaintiffs respectfully  
26 request that this Court:  
27

- 1) Stay the new regulations pertaining to the medical exemption from school immunization requirements codified in 10 NYCRR §66-1;
- 2) Enjoin defendants from excluding children from school due to lack of immunization if such child has presented a certification from a licensed physician advising against such immunization; and
- 3) Order the Defendants to provide notice to schools, districts, and families that Plaintiffs and similarly situated children may attend school and access federally protected programs; and
- 4) Issue a temporary restraining order granting the same relief for fourteen days from the start of school pending hearing on the motion; and
- 5) For such other and further relief as the Court deems just and appropriate.

Dated: August 24, 2020

Respectfully submitted,

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